

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton of 1, 2, 3, 4 or 6 pipettes containing 4.02 ml pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Fipronil and (S)-Methoprene 402 mg / 361.8 mg spot-on solution for very large dogs
Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs (UK)
fipronil
S-methoprene

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

What is in this medicine?

One 4.02 ml pipette contains:

402 mg fipronil
361.8 mg (S)-methoprene
0.8 mg butylhydroxyanisole (E320)
0.4 mg butylhydroxytoluene (E321)

3. PHARMACEUTICAL FORM

Spot-on solution.

4. PACKAGE SIZE

1, 2, 3, 4 or 6 4.02 ml pipettes.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

What is this medicine used for?

To be used against infestations with fleas, alone or in association with ticks and/or biting lice.

- Kills fleas (*Ctenocephalides* spp.) on treated dogs for up to 8 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 8 weeks.

- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*) on treated dogs for up to 4 weeks.
- Kills biting lice (*Trichodectes canis*).

Read the package leaflet carefully before each use. Keep the leaflet and any unopened sachets in the carton until required.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How do I use this medicine?

For external use only. Spot-on use.

For dogs weighing over 40 kg.

Read the package leaflet before use.

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

Always leave a minimum period of 4 weeks between treatments.

8. WITHDRAWAL PERIODS

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

This product is specifically developed for dogs. Do not use in cats or ferrets, as this could lead to overdosing.

Do not use this product:

- On puppies less than 8 weeks old and/or weighing less than 2 kg.
- On sick (e.g. systemic diseases, fever) or convalescent animals.
- On rabbits, as adverse reactions, including death, could occur.
- On species other than dogs.
- If your pet is hypersensitive (allergic) to the active substance or to any of the excipients.

User Safety Warnings

Please read before every use

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided. In case of accidental eye contact, immediately and thoroughly rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician. If contact with the skin occurs, wash hands with soap and water.

People with a known hypersensitivity (allergy) to Fipronil, (S)-Methoprene, alcohol or excipients should avoid contact with the veterinary medicinal product.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use. Do not smoke, drink or eat during application.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product, seek medical advice immediately.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in watercourses for 2 days after application.

Please read the package leaflet provided before every use.

Keep pipettes in original packaging and dispose of used pipettes immediately.

10. EXPIRY DATE

EXP: mm/yyyy

11. SPECIAL STORAGE CONDITIONS

How should this medicine be stored?

Store in the original package in order to protect from light and moisture.
Keep pipettes in the original packaging until ready to use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Dispose of waste materials in accordance with local requirements. Fipronil and (S)-methoprene may adversely affect aquatic organisms, do not contaminate ponds, waterways or ditches with the product or empty containers.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4416

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet for 4.02 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Fipronil and (S)-Methoprene 402 mg / 361.8 mg spot-on solution for very large dogs
Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs (UK)
fipronil
S-methoprene

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

What is in this medicine?

One 4.02 ml pipette contains:

402 mg fipronil
361.8 mg (S)-methoprene

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4.02 ml

4. ROUTE(S) OF ADMINISTRATION

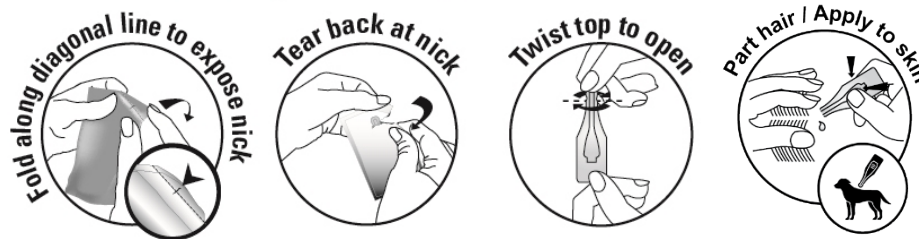
How do I use this medicine?

Spot-on use.

Only remove pipette from sachet immediately prior to use.

<Pictogram of a spot-on pipette>

To remove from sachet please use scissors or



5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP: mm/yyyy

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Dog <Pictogram of a dog>.

9. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited.



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MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

4.02 ml pipette/blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Fipronil and (S)-Methoprene
Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs (UK)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook

3. EXPIRY DATE

mm/yyyy

4. BATCH NUMBER

XXXX XXX

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

<Pictogram of a dog>

6. PHARMACEUTICAL FORM

<Pictogram of a spot-on pipette>

7. Active Content

402 mg / 361.8 mg

8. VOLUME

4.02 ml

9. TARGET ANIMAL WEIGHT RANGE

> 40 kg



B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Norbrook Fipronil and (S)-Methoprene 4.02 mg / 361.8 mg spot-on solution for very large dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbrook Fipronil and (S)-Methoprene 402 mg / 361.8 mg spot-on solution for very large dogs
Fleanil Duo 402 mg / 361.8 mg Spot-on Solution for Very Large Dogs (UK)
fipronil
S-methoprene

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each pipette of 4.02 ml contains:

Active substances:

Fipronil	402 mg
(S)-methoprene	361.8 mg

Excipients:

Butylhydroxyanisole (E320)	0.8 mg
Butylhydroxytoluene (E321)	0.4 mg

A clear, yellow solution.

4. INDICATION(S)

For the treatment of dogs weighing over 40 kg bodyweight:

The product is used for the treatment of infestations by fleas, ticks and biting lice in dogs.

- Kills fleas (*Ctenocephalides* spp.) on treated dogs for up to 8 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 8 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*) on treated dogs for up to 4 weeks.
- Kills biting lice (*Trichodectes canis*).

5. CONTRAINDICATIONS

Do not use on puppies less than 8 weeks old and/or weighing less than 2 kg.

Do not use on sick (e.g. fever) or convalescent animals.

Do not use in rabbits, as adverse reactions including death, could occur.

Do not use in species other than dogs.

This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.

Do not use in known cases of hypersensitivity (allergy) to the active substance or to any of the excipients.

Do not use simultaneously with other flea products which are applied directly on to the animal.

6. ADVERSE REACTIONS

In very rare cases, temporary skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

The frequency of adverse reactions is defined using the following convention:

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If licking occurs, a brief period of excessive salivation may be observed due mainly to the nature of the carrier .

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

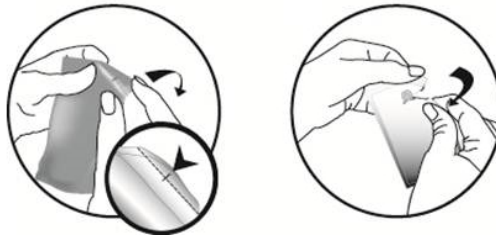
Dosage: one pipette of 4.02 ml per dog weighing over 40 kg, corresponding to a minimum recommended dose of 6.7 mg/kg for fipronil and 6 mg/kg for (S)-methoprene.

Do not overdose.

Route of administration: External use only, spot-on use.
Only remove pipette from sachet immediately prior to use.

Method of Administration:

Remove the pipette from the outer sachet using scissors or fold along diagonal line to expose nick; tear back at nick.



Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette. Twist or snap back the tip.



Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

9. ADVICE ON CORRECT ADMINISTRATION

Animals should be weighed accurately prior to treatment.

It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

Avoid contact with the animal's eyes.

Always leave a minimum period of 4 weeks between treatments.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original package in order to protect from light and moisture.

This veterinary medicinal product does not require any special temperature storage conditions.

Do not use after the expiry date stated on the sachet and carton.

12. SPECIAL WARNING(S)

For Animal Treatment Only.

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided as it is unknown how this affects the effectiveness of the product. Emollient shampoos can be used prior to treatment, but when used weekly after application of the product, they reduce the duration of protection against fleas to approximately 5 weeks. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect reduce effectiveness of the product against fleas during a 6 week long study.

There may be an attachment of a few ticks. For this reason transmission of tick-borne diseases cannot be completely excluded if conditions are unfavorable.

When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time. Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the house should be treated with a suitable insecticide.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Keep pipettes in original packaging and dispose of used pipettes immediately.

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided. In case of accidental eye contact, immediately and thoroughly rinse the eyes with clean water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician. If contact with the skin occurs, wash hands with soap and water.

People with a known hypersensitivity (allergy) to Fipronil, (S)-Methoprene, alcohol or excipients should avoid contact with the veterinary medicinal product.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.

Wash hands after use. Do not smoke, drink or eat during application.

Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product. In case of accidental ingestion of product, seek medical advice immediately.

Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

Pregnancy and Lactation:

The product can be used during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes):

The risk of experiencing adverse effects may increase when overdosing (see section 6. Adverse Reactions), so animals should always be treated with the correct pipette size according to bodyweight.

Other precautions

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

The alcohol carrier may have adverse effect on painted, varnished or other household surfaces or furnishings.

This product is flammable. Keep away from heat, sparks, open flame or other sources of ignition.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

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Packaging Information:

4.02 ml pipette, moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminate and a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachet composed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.

Boxes of 1, 2, 3, 4 or 6 pipettes. Each pipette is individually sealed in a foil sachet.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 22 October 2020

